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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,656	09/18/2001	Charles A. Nicolette	GZ 2096.00	1157

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EXAMINER	
MYERS, CARLA J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,656	NICOLETTE ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 10-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed 10/14/05. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

THE FOLLOWING INCLUDES NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 6, 13, 16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5 and 13 are indefinite over the recitation of the phrase "wherein said characterization of the gene product further comprises the property of molecular weight" because it is unclear as to how this phrase is intended to further modify the claims. The claims do not clearly state the relationship between molecular weight and the remainder of the claim. For instance, it is unclear as to whether this phrase refers to the fact that molecular weight is a property of the gene products or whether the claim is intended to include a step in which the molecular weight is determined in addition to one of the stated properties or as a substitute for one of the stated properties.

Claim 6 is indefinite because it depends from cancelled claim 6. For the purposes of compact prosecution, this claim has been examined to the extent that it depends from

claim 1. However, in response to this amendment, the claim should be amended to depend from a pending claim.

Claims 16 and 19 are indefinite over the recitation of "The method....further comprising samples" because it is unclear as to how this phrase is intended to further limit the claims. Since the claims are directed to methods, it is unclear as to how the methods comprise a sample. Accordingly, it is unclear as to whether the recited phrase is intended to further define the sample that is to be analyzed or whether the phrase is intended to further define a step of obtaining the samples.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, and 10-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tureci (Hybridoma. 1999. 18: 23-28; cited in the IDS of 2/26/2002).

Tureci (see, e.g., page 25) teaches a method for identifying a polypeptide correlated with the phenotype of cancer wherein the method comprises: (a) binding polypeptides obtained from sample cell clones to serum antibodies obtained from a cancer patient (i.e., a subject with a phenotype); (b) charactering the polypeptides in the sample with respect to their binding reactivity to the serum antibody and with respect to their sequence; (c) obtaining gene expression profile data from the sample wherein the genes are characterized by properties of the gene's product, wherein said properties

include reactivity with the serum antibody, and expression levels in normal tissues and in cancer tissues; and (d) selecting a polypeptide that is encoded by the gene of (c) to thereby identify a polypeptide correlated with the phenotype of cancer. In particular, Tureci teaches that the polypeptides are characterized with respect to their reactivity to sera from healthy controls and allogeneic tumor patients (page 25 and Table 4). Additionally, Tureci (page 25) teaches that expression data was obtained in normal tissues and tumors by RT-PCR and by analysis in expressed sequence tag containing databases. The gene expression profile included the characterization of polypeptides as being "aberrantly expressed in human tumors" (i.e., unique expression) and overexpressed in certain human tumors (see Table 3 and pages 26-27). With respect to claims 3-5, 12 and 13, t is a characteristic of the polypeptides identified by Tureci that they have 2 or more properties, including the property of molecular weight. With respect to claim 10, it is noted that the claim does not require performing a step of MALDI-TOF analysis. Rather, the claim further defines the selection criteria for MALDI-TOF, but does not require that one of the analyzed properties includes MALDI-TOF. With respect to claim 11, the method of Tureci is one in which the polypeptide in the sample is analyzed with respect to its reactivity with serum antibodies obtained from a cancer patient and serum antibodies from normal subjects (i.e., subjects without the phenotype of cancer). Further, the identified polypeptides were not bound by serum from subjects without the phenotype of cancer (see page 26 and Table 4). With respect to claims 14-19, Tureci teaches the analysis of a multitude of samples obtained from patients having the similar phenotype of cancer.

Response to Arguments:

In the response, Applicants traverse this rejection by stating that Tureci does not teach step c) of the claims as amended. It is stated that "No gene expression profiles were obtained for the samples against which the serum antibody is screened."

Applicant's arguments have been fully considered but are not persuasive because Tureci does in fact teach the limitations set forth in step c). In particular, Tureci teaches obtaining gene expression profile data consisting of properties of the gene's product, wherein the properties include specific reactivity with serum antibodies (see Table 4 and pages 26-27). Further, Tureci (page 25 and Table 3) teaches that the expression levels of the gene's product were characterized with respect to whether the products were highly expressed in the sample or uniquely expressed in the sample. For instance, Tureci (pages 26-27) states that "Clones occurring rarely in est (expressed sequence tag) databases of normal tissue were processed with priority, as this suggested a restricted expression pattern. Expression patterns for each clone were assessed by RT-PCR with transcript specific oligonucleotides chosen to hybridize with two different exons. Northern blot hybridization with labeled cDNA inserts as probes was performed to determine the quantitative level of mRNA abundance. Here again, four different groups could be defined. The first group represented transcripts with selective expression in tumors...A second group of antigens was represented by differentiation antigens...A prominent group is represented by antigens that are overexpressed in tumors compared with their normal counterpart tissue." Accordingly, Tureci does teach each of the limitations of the claims, and particularly teaches the

limitation of step c) of obtaining gene expression profile data wherein the genes are characterized by the properties of the gene's product, wherein the properties are highly expressed in a sample or uniquely expressed in a sample.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
December 12, 2005

CARLA J. MYERS
PRIMARY EXAMINER